DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2001

Mr. John C. Radke
Bio-Research Associates, Incorporated
4113 North Port Washington Road
Milwaukee, Wisconsin 53212

Re: K003176
Trade Name: BioEMG II and BioJVA
Regulatory Class: Unclassified
Product Code: KZM and KZO
Dated: October 6, 2000
Received: October 11, 2000

Dear Ms. Radke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K003176
Device Name: **BioEMG II / BioJVA**
Indications for Use:

At the present time, comparisons between patients of electromyograms, sonograms and / or jaw traces should not be made.

Sufficient normative data have not been collected to support such population-based measurements as "mean electromyographic clench," "standard deviation (Jaw Tracking) of freeway space," "integral (sonograph) of sound intensity," "average jaw tracing of chewing," etc., for non diseased individuals as well as for patients having various disease entities that are now lumped within the terminology known as "Temporomandibular Disorders and Associated Orofacial Pain (TMD/MPD)."

Electromyography

1. To record electrical activity of muscles of the stomatognathic system, especially temporalis, masseter and digastric
2. To clinically monitor up to eight different muscles as an aid in diagnosis and treatment evaluation by recording the electrical activity of the muscles of the stomatognathic system.
3. To determine the degree of relaxation (intra-patient) of a single muscle / group of muscles at rest
4. To measure relative (intra-patient) levels of activity of several muscles during a functional act

Sonography, joint vibration (sound) recording

1. To record and display sounds / vibrations from the temporomandibular joint
2. To aid the clinician in his analysis of a joint sound / vibration by allowing him to see the waveform in various standard plots
3. To aid the clinician in comparing a patient's current standard plots to previous recordings before, during and after treatment
4. To provide numerical values that can be used to quantify the physical characteristics of the sounds / vibrations, allowing intra-patient comparisons (only) by the clinician

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003176

(Optional Format 1-2-96)